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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,040	02/20/2002	Peter L. Ryan	RU-0176	6411

7590

12/30/2003

Licata & Tyrrell P.C.  
66 E. Main Street  
Marlton, NJ 08053

EXAMINER
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DAVIS, DEBORAH A

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 12/30/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/079,040

Applicant(s)

RYAN ET AL.

Examiner

Deborah A Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 September 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

1. Applicant's response to the Office Action mailed May 20, 3003 (Paper #5) is acknowledged. Currently, claims 1-2 are amended and under consideration.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Stewart et al (Breed Differences in circulating Equine Relaxin, Biology of Reproduction, 1992, Vol. 46, pages 648-652).

Stewart et al anticipates claims 1-2 by teaching a method for measuring levels of relaxin in plasma of a pregnant mare before and after the administration of a drug or treatment (see abstract and introduction) wherein a homologous equine relaxin Radio Immunoassay (RIA) has been developed and used to measure plasma relaxin activity in thoroughbred mares during gestation until the time of foaling. Burros and Thoroughbred mares stimulated to deliver with oxytocin (treatment) showed an elevation in relaxin levels wherein the sensitivity to oxytocin (treatment) appears to develop late in gestation, as mares induced to abort in midpregnancy did not show a rise in relaxin (page 651, column 2, paragraph 2). Animals that exhibited adverse pregnancy outcomes had

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depressed relaxin concentrations at some point during gestation prior to the loss (page 651, column 2, paragraph 2). With respect to claim 2, the preamble recites a diagnostic kit, but will not be given patentable weight because the content of the kit is not clear and the language is considered to be intended use. Therefore, the instant reference reads on a diagnostic kit wherein it teaches detecting relaxin levels in a radioimmunoassay.

### ***Response to Arguments***

4. Applicant's arguments filed September 19, 2003 have been fully considered but they are not persuasive.

Applicant asserts that Examiner's suggestion that the Stewart et al reference describes measurement of relaxin before and after a drug treatment as claimed is incorrect. This argument is not found persuasive because Stewart et al administered the drug oxytocin before and after relaxin levels were measured (see abstract and introduction).

Applicant's argument that the drug oxytocin in the reference of Stewart et al is not used to treat a disease or condition that alters placental function but instead is used simply to induce normal delivery of a foal is not found persuasive. The Stewart et al reference demonstrated a positive correlation between relaxin and placental functions, wherein relaxin can be used to assess at risk pregnancy in mares (see abstract). Mares treated with the drug oxytocin were induced to foal showed elevated levels of relaxin opposed to those that aborted which exhibited depressed levels of relaxin (page 651, column 2). Therefore, the

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reference of Stewart et al anticipates the instant claims and the rejection is maintained.

Applicant has provided a declaration signed by inventors who have declared that the reference of Ryan et al cited in a 102(a) rejection against the instant claims was their own work and not of another. The declaration is found persuasive and is hereby withdrawn.

### ***Conclusion***

No claims allowed.

**5. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is

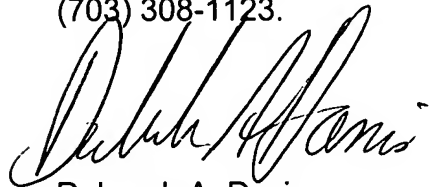
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(703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

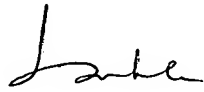
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is

(703) 308-1123.



Deborah A. Davis  
CM1, 7D16  
December 18, 2003

  
LONG LE  
SUPERVISORY PATENT EXAMINER  
DEC 17 2003

h/24/03